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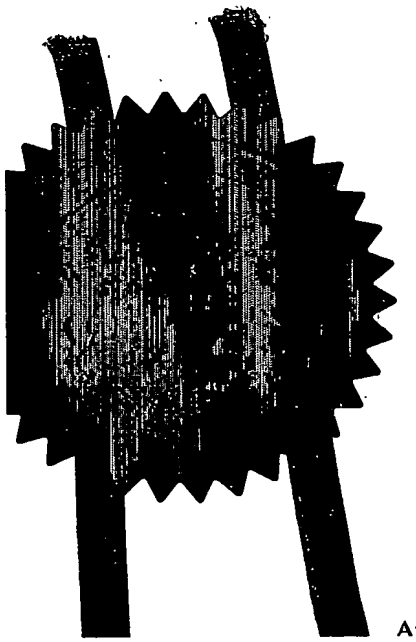

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15 JAN 2003
16JAN03 E777342-4 D02656
P01/7700 0.00-0300915.6

2. Patent application number *(The Patent Office will fill in this part)* — 0300915.6

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

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Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

TRANS-LUMINAL SURGICAL DEVICE

5. Name of your agent *(if you have one)*

David Lethem

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

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Patents ADP number *(if you know it)*

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Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

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12. Name and daytime telephone number of person to contact in the United Kingdom

David Lethem
Hoffmann Eitle

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Trans-Luminal Surgical Device

Technical Field

This invention relates to a trans-luminal surgical device and more particularly, but not exclusively, to a stent pusher assembly, and to a delivery system having a rapid-exchange configuration for deploying a self-expanding stent at a stenting site within a human or animal body.

Background Art

EP-A-1 095 634 (EP 634) discloses a rapid-exchange, self-expanding stent delivery system. EP 634 discloses a system in which the soft atraumatic distal tip of the system is at the leading end of the inner catheter. The outer sheath of the delivery system has a distal end which stops proximally short of the atraumatic tip.

Stents to be deployed at a stenting site within a human or animal body expand radially in the course of delivery, from a radially compact delivery disposition to a radially larger deployed disposition. In self-expanding stents made of stainless steel, the deformation of the stent is below the elastic limit, the stent until its deployment being radially confined and under elastic stress and typically released by proximal withdrawal of a confining sheath while the stent is itself prevented from moving proximally with the confining sheath by abutment with a stop on the distal end of a catheter shaft which suffers axial compressive stress while the surrounding sheath is proximally withdrawn.

By contrast, stainless steel stents which are relaxed in a radially compact disposition suffer plastic deformation when expanded into their deployed disposition by inflation of a balloon within the lumen of the stent.

An early example of stainless steel self-expanding stents is Gianturco US-A-4,580,568 and an early example of the balloon expansible stainless stent is Palmaz EP-A-221 570.

A third category of stent is the memory metal stent, made of a biologically compatible nickel-titanium shape memory alloy with martensitic and austenitic phases. At body temperature, the stent "seeks" to revert to the austenitic phase. Typically it is confined within a surrounding sheath and again released at the stenting site by proximal withdrawal of this sheath.

The present invention offers improvements in systems to deliver those stents which are brought to the stenting site within a confining surrounding sheath.

In the technical field of stenting, there is a desire to reduce the transverse dimensions of the stent delivery system. In this field, the widely used measure of transverse cross-section is the unit of "French", often abbreviated to "F" which is a one third part of a millimeter. Thus, a 6 French (6F) delivery system has a diameter of 2 millimeters.

For any particular stenting operation, one has to select a particular stent and a particular delivery system. There is a large choice in both of these elements. Accordingly, it would be an advantage for manufacturers of stents and their delivery systems to achieve a degree of modularity in the design and construction of stents and their delivery systems. For example, there is a wide range of stents which could be delivered by a 6F delivery system and it would therefore be convenient for the manufacturer of a stent delivery system to be able to tailor a basic 6F system to fit any particular stent which would be compatible with a 6F delivery system. This would reduce costs, to the advantage of patients, while retaining full flexibility for medical practitioners to optimise their choice of stent for any particular patient.

Like many catheter systems and trans-luminal surgical devices, a stent delivery system is often used with a flexible

guidewire. The guidewire is preferably made of metal, and is slidably inserted along the desired body passage. The delivery system is then advanced over the thus pre-placed guidewire by "backloading" or inserting the proximal end of the guidewire into a distal guidewire port leading to a guidewire lumen defined by the delivery system.

Many conventional trans-luminal surgical devices delivery systems define guidewire lumens that extend along the entire length of the outer sheath. These delivery systems are described as "over-the-wire" delivery systems, in that the surgical device is guided to the site of the surgery over the guidewire, the guidewire thereby exiting the delivery system at the proximal end of the delivery system. "Over-the-wire" delivery systems provide several advantages, including improved trackability, the ability to flush the guidewire lumen while the delivery system is inside the patient's body, and easy removal and exchange of the guidewire while the delivery system remains in a desired position in the patient.

In some circumstances, however, it may be desirable to provide a "rapid exchange" delivery system, which offers the ability more easily to remove and exchange the delivery system while retaining the guidewire in a desired position within the patient. In a rapid-exchange delivery system, the guidewire occupies a lumen located only in the distal portion of the delivery system. The guidewire exits the delivery system through a proximal guidewire port, closer to the distal end of the delivery system than to its proximal end, and extends in parallel along the outside of the proximal portion of the delivery system.

Because a substantial length of the guidewire is outside the delivery system, it may be manually held in place close to the point where it passes the entry point on the body of the patient, as the delivery system is removed. This facilitates handling, removal and exchange of the delivery system for the practitioner for the following reasons.

With a guidewire lumen that is much shorter than the full catheter length a single physician can insert and remove a stent (or other surgical device) delivery system into and from the patient's body. Whereas conventional delivery systems require a guidewire having a length at least double the length of the outer catheter, the rapid-exchange configuration allows the use of much shorter guidewires which enable a single physician to handle the proximal end of the guidewire at the same time as the catheter at the point of its entry into the body of the patient.

Accordingly, the present invention advantageously provides a stent delivery system having a rapid-exchange configuration for delivering and deploying a self-expanding stent or other trans-luminal surgical element, or performing a surgical procedure in a percutaneous, trans-luminal manner.

Stents themselves cannot be directly seen during their journey to the stenting site, nor can one directly see whether the stent is exactly located as desired within the stenting site. Rather, indirect means have to be used to follow the progress of the stent through the body and make sure that it is correctly located before it is deployed. Thus, the device delivery system is used during deployment to carry radiopaque contrast or marker fluid to the site of surgery so that the target site can be seen through the radiopaque fluid in the bodily lumen at the site. This radiopaque fluid is generally injected through an injection port at the proximal end of the delivery system and through an annular space between an outer sheath of the delivery system and a proximal portion of an inner catheter shaft. The visibility of the site is adversely affected when the lumen, through which radiopaque contrast fluid is injected, is too small at the site to deliver a strong pulse of contrast fluid. As pulses of fluid are used for visualisation, the effectiveness of visualisation depends on the volume flow in each pulse. This in turn depends on the ease of flow of the fluid along the full length of the delivery system, from the point of injection at the proximal end, to the site of surgery beyond the distal end of the delivery system.

Thus, delivery systems which offer a large cross-section and unimpeded lumen for contrast fluid will be favoured by radiologists, other things being equal. The visibility can additionally be increased by further reducing the resistance of the system to pulses of contrast fluid. It is therefore an object of the present invention to provide good visualisation with contrast fluid, without sacrifice of other important performance aspects of the delivery system, including pushability and low overall diameter. By increasing "pushability" we mean the capability to be advanced longer distances along narrower and more tortuous bodily lumens.

Furthermore, the delivery system invariably carries at least one radiopaque marker at a known location relative to the length of the surgical device (such as a stent), so that radiologists can be sure of the location of the ends of the device, on the basis of their knowledge of the location of the radiopaque marker. Even if the device is rendered sufficiently radiopaque for it to be seen, it is still useful to have a radiopaque marker on the distal end of the delivery system, to reveal for example successful separation of the device from the delivery system.

Thus, in our example of a 6F delivery system, to be used for delivering stents of various lengths, there will be a wish to provide radiopaque markers within the delivery system at two spaced-apart locations on the axis of the delivery system, corresponding to the opposite ends of the stent (until the stent is deployed out of the system). One object of the present invention is to offer a degree of modularity in this design aspect.

With delivery systems having a rapid-exchange configuration, just as with over-the-wire systems, the delivery system is advanced over the guidewire, itself normally within a guide catheter, in order to bring the distal tip and surgical device to the site of surgery. Depending on the application, different diameter guidewires are specified. Two commonly used

guidewire diameters are 0.46 mm/0.018 inches and 0.89 mm/0.035 inches (commonly known as 18 thou or 35 thou guidewires). Thus, a further degree of modularity can be achieved by offering a delivery system which is compatible with a range of guidewire diameters, specifically, both 18 thou and 35 thou guidewires.

Naturally, it would be an advantage for any new stent delivery system to be able straightforwardly to take the place of those previous delivery systems which individual practitioners have grown to be comfortable using. One such system uses in its proximal portion a metallic rod, which can be either solid or hollow, made of stainless steel.

Further, it goes almost without saying, that good design for delivery systems for surgical devices such as stents is indicated by manufacturing steps which can be performed with high precision and reliability, yet with acceptable cost levels. This is yet another objective of the present invention.

Finally, for any system which is extremely long in proportion to its diameter, and features at least three co-axial elements, the cylindrical surfaces of these co-axial elements need to be so composed and conformed that friction between them is low enough that the co-axial elements can be moved tolerably easily axially relative to each other. It is yet another object of the present invention to provide systems which offer possibilities for bringing these friction levels down to advantageously low levels.

Along with all these issues already appreciated by those skilled in the art, there is a further performance aspect which becomes evident when a self-expanding stent is released progressively by successive proximal stepwise movements of the outer confining sheath.

Typically, the delivery system is extremely long in proportion to its cross-sectional dimensions, and is constructed

predominantly or wholly from synthetic polymeric materials which have substantial elasticity and marked kinetic aspects to their deformation characteristics. In such a case, any particular rate of strain imposed on the proximal end of the outer sheath is likely to be experienced at the distal end of the same sheath in a somewhat different strain rate. For example, a fast squeeze of the trigger of a deployment system at the proximal end of the sheath will likely result in a somewhat slower resulting proximal advancement of the distal end of the same sheath. Furthermore, a pull on the sheath will impose compressive stresses along the length of the inner shaft, likely leading to a proximal movement of the stent which then relaxes back to the original, more distal, position of the stent as the tensile stress in the outer sheath eases back towards zero. In its own delivery systems, Applicant has observed what happens at the distal end of a stent delivery system during successive squeezes of the trigger of a delivery system which pulls the outer sheath proximally in a series of steps. The appearance at the stent end of the system is as if the system were "breathing" in that it, and the stent, moves axially first proximally, then distally, with each squeeze of the trigger.

This "breathing" phenomenon is of course a complicating factor when it comes to precision of intra-luminal placement of a stent (or other surgical element) within any particular luminal site of surgery. It is yet another object of the present invention to ameliorate this problem.

These and other objects are solved by an intra-luminal surgical element deployment system disclosed in Applicant's earlier PCT/EP02/07435 (about to be published). For placement of a stent, the system may include an annular pusher element which abuts the stent to stop it moving proximally when the outer sheath is withdrawn proximally to release the stent.

In one embodiment of the system disclosed in PCT/EP02/07435 there is included a pusher assembly for a delivery system for a self-expanding stent, the pusher assembly constituting a

catheter shaft with a proximal pusher end to receive an end-wise compressive force and a distal pusher end to deliver said force to a stent to be delivered, the pusher assembly comprising a pusher strand extending from the proximal pusher end to a distal strand end which is nearer the distal pusher end than the proximal pusher end; a pusher element which abuts the stent in use to deliver said force to the stent; and a transfer shaft having a proximal and a distal end, the proximal end being connected to the distal tube end and the distal end being connected to the pusher element and wherein the pusher element defines a guidewire path, and the transfer shaft lies to one side of said path.

By contrast, in conventional systems such as that of EP 634 in which the atraumatic tip is carried on the inner catheter, the pusher element is mounted on a tube which has a guidewire lumen and extends distally all the way to the tip.

Embodiments of the system of PCT/EP02/07435 provide a stent delivery system having a rapid-exchange configuration for a self-expanding stent which provides improved visualisation through an increased volume flow in each pulse of radiopaque contrast medium pumped through the device. The volume flow in each pulse is increased in the present invention due to a simplified and reduced internal structure of the delivery system.

The fundamental disclosure of Gianturco US-A-4,580,568 is represented herein by accompanying drawing Fig. 1. Referring to Fig. 1, the essential features of a basic delivery system are an outer sheath 4 confining the stent 6 in a radially compressed state and a pusher element 8 preventing proximal movement of the stent when the outer sheath 4 is proximally withdrawn. The pusher element is carried on an inner catheter shaft 3. Here, the delivery system is inserted over a guidewire 2 into a lumen of a human or animal body.

A preferred embodiment of the system of PCT/EP02/07435 recovers much of the simple delivery concept of Fig. 1 by shortening the

inner catheter shaft so that its distal end is relatively close to the proximal guidewire lumen exit port. By contrast, in the by now conventional tip arrangement of a self-expanding stent delivery system the inner catheter shaft 3 extends more distally, even beyond the distal end of the stent 6, to provide a tapered tip, for ease of insertion of the delivery system into the patient's body and for reducing trauma whenever the catheter is advanced distally. Above-mentioned EPO 634 discloses a stent delivery system which conforms to this conventional model.

In preferred embodiments of the system of Applicant's PCT/EP02/07435, the stent pusher element carries a carrier tube which is used to define at least a short distal guidewire lumen. Further, a system tip taper on the distal end of the outer sheath, renders redundant the need for an atraumatic distal tip on the inner catheter distal of the stent. Therefore, the internal structure of the delivery system is more open, which consequently enhances ease of flow and the volume of contrast fluid that can be ejected from the distal end of the delivery system with each successive pulse imposed from the proximal end of the delivery system. Hence, visualisation is improved.

The manufacturing and assembling steps required to get the delivery system ready for use are minimised due to the simplified internal structure. No longer is there a necessity for keeping the stent at a fixed position on the inner catheter shaft while the outer sheath is fitted over the stent. Also, the risk of advancing the stent too far distally and out of the distal opening of the outer sheath during assembly of the delivery system is minimised, since the outer sheath preferred in embodiments of PCT/EP02/07435 comprises the tapered tip which acts as a distal stopper for the stent during assembly. Also, it is worthwhile to note that there are fewer steps during manufacturing and assembly of the stent delivery system, which itself is a valuable gain in this technical field.

The introduction of a stent using a preferred embodiment of the stent delivery system of PCT/EP02/07435, and subsequent removal of the delivery system, is facilitated especially in tortuous vessels and other body lumens having a relatively narrow diameter because, once the stent has been placed at a desired site inside the patient's body, there need be no component of the delivery system which is radially inwardly located from the stent and which has to be proximally withdrawn through the stent lumen. Especially in narrow and sharply curved body vessels, this might introduce a risk that the distal tip being withdrawn through the stent lumen interferes with bodily tissue protruding radially inwardly through the interstices of the stent and into the stent lumen. A preferred delivery system avoids this problem by providing the tapered tip on the distal end of the outer sheath so that, during removal of the delivery system out of the patient's body, there need be no system components which travel proximally within the stent lumen and are likely to engage with the inner surface of the stent.

In one preferred embodiment, the pusher element is a cylinder which has a distal-facing end face at the distal end of the cylinder to push on the proximal end of the stent. Thus, the end face will likely be flat and transverse to the axis of the cylinder. The pusher element can serve as, and preferably does serve as, a radiopaque marker.

If desired, the pusher element can also serve as a mount for a distal marker carrier tube cantilevered distally forward from the pusher element to lie within the space that will correspond to the lumen of the stent to be deployed by the system. This is useful when it is required to have on the delivery system a radiopaque marker for the distal end of the stent. This radiopaque marker can be placed on the carrier tube at a position at or towards the distal end of the carrier tube and corresponding to the distal end of the stent. For stents of different lengths, the length of the carrier tube can easily be varied to correspond to the stent length, prior to fixing the distal marker on the carrier tube.

It will be appreciated that the carrier tube requires relatively little strength, so can be made thin and flexible, thereby reducing the risk of its interfering with tissue protruding through the stent during its withdrawal from the stenting site.

As the carrier tube is a relatively simple and isolated part of the delivery system, and conveniently made of a synthetic polymeric material, it will be a relatively simple matter to change the length of the carrier tube to suit any particular stent destined to be carried on the system. If desired, the carrier tube can be extended backwardly proximally from the pusher element and given an end flared outwardly proximally. This flared end provides security against the possibility of unwanted slippage of the carrier tube distally through the pusher element and of being left behind in the body when the delivery system is withdrawn. It may also be useful to guide the guidewire through the system whenever there is need to introduce the distal end of the guidewire from the proximal end of the system.

Another option for modularisation is given by a transfer shaft connecting the rod or inner catheter with the pusher element. This can be set to any desired length, to accommodate stents of different length in a delivery system which features standard length catheter components such as the sheath, rod or inner catheter and pusher tube. It may be convenient to use a welded joint to fasten one or both of the two ends of the transfer shaft to the pusher element and rod, respectively.

For a better understanding of the system of PCT/EP02/07435, and to show more clearly how the same can be carried into effect, reference will now be made, by way of example, to the accompanying drawings of embodiments of the delivery system disclosed in PCT/EP02/07435 (about to be published as a WO document)

Brief description of the drawings from PCT/EP02/07435

Fig. 1 shows in longitudinal axial section the distal portion of a prior art delivery system;

Fig. 2 is a cross-section of the distal portion of a delivery system having a rapid-exchange configuration in accordance with a preferred embodiment of PCT/EP02/07435;

Fig. 3 shows an isometric view of the adapter having two lumens effecting the rapid exchange configuration;

Fig. 4 shows a cross-section of the proximal portion of the delivery system, the pull-back device used to proximally retract the outer sheath, in accordance with a preferred embodiment;

Fig. 5 shows a cross-sectional view of the distal portion of an over-the-wire pusher assembly according to a second embodiment;

Fig. 6 shows a cross-sectional view of the distal portion of another over-the-wire pusher assembly according to a third embodiment;

Fig. 7 shows a cross-sectional view of the distal portion of yet another over-the-wire assembly, being a fourth embodiment of PCT/EP02/07435;

Fig. 8 shows at larger scale the distal tip portion of the Figure 7 embodiment; and

Fig. 9 shows at the scale of Figure 8 a part of the Figure 7 distal portion which is proximal of the tip shown in Figure 8.

The following description of the preferred embodiments of PCT/EP02/07435 is merely to provide technical background to the

present invention, and as such does not limit in any way the present invention, its application, or uses.

Fig. 2 shows a cross-section of the distal portion of a delivery system having a rapid-exchange configuration in accordance with a preferred embodiment of the system disclosed in PCT/EP02/07435.

In Fig. 2, a guidewire 2 extends beyond the distal end of the distal portion of the delivery system along which the stent delivery system is advanced to the site of the stenosis inside the patient's body. The stent 6 is held in a radially compressed state by means of an outer sheath 4 the distal end of which constitutes the distal end of the stent delivery system. The distal tip 4A of the outer sheath 4, as shown in Fig. 2, is tapered in order to facilitate advance of the stent delivery system along a bodily lumen. Furthermore, the outer sheath 4 comprises a radiopaque marker 27 the position of which is indicative for the distal end of the stent until deployment of the stent. The guidewire 2 extends all the way through the outer sheath lumen and exits the distal portion of the stent delivery system at a proximal guidewire port 24.

A pusher element 8 abutting the stent 6 in use of the delivery system prevents proximal movement of the stent 6 when the outer sheath 4 is withdrawn proximally to release the stent. The pusher element 8, which at the same time serves as a proximal radiopaque marker, is connected to a transfer shaft 12. The pusher element 8 is preferably laser-welded to the distal end of the transfer shaft 12. For ease of connection the distal end of the transfer shaft 12 is tapered and embedded in a respective slot provided in the proximal end of the pusher element 8. The distal end of the transfer shaft 12 is tapered, and the transfer shaft 12 is corresponding oblate at its distal end, so that the distal end of the transfer shaft 12 can be fitted into a respective slot of the adjacent pusher element 8, with the circumferential surface over a specific arc length of the oblated end being flush with the circumferential surface of the pusher element 8. The slot provided in the proximal end of

the pusher element 8 has an axial length which extends from the proximal end of the pusher element 8 beyond midway along the axial length of the pusher element 8. This ensures a sufficiently rigid connection of the transfer shaft 12 with the pusher element 8. Such shaping of the distal end of the transfer shaft 12 and the pusher element 8 optimises the flow of injected contrast fluid F, since the fluid does not meet any unnecessary barrier when travelling along the length of the transfer shaft 12. In this way, the flow resistance of the injected contrast fluid F is minimised.

The transfer shaft 12 is capable of receiving an endwise compressive force C and transmitting the force C to the proximal end of the stent 6, thereby preventing proximal movement of the stent 6 when the outer sheath 4 is withdrawn proximally by imposition of tensile force T on the sheath 4. The arrows in Figure 2 are indicative for the direction of the respective forces T and C.

A connection piece 14, such as a tube, at the proximal end of the transfer shaft 12, as shown in Fig. 2, enables the accommodation of different stent lengths in an unchanged sheath 4 by an appropriate adjustment in the length of the transfer shaft 12 in accordance with the length of the respective stent 6.

The cut-to-length transfer shaft end within the connection tube 14 is glued or soldered to the connection tube 14. The proximal end of the transfer shaft 12 is directly connected to the distal end of an inner shaft tube or rod 16 by means of a solder joint or glue. Otherwise, the connection tube 14 can be no more than a collar into which two adjacent ends of separate transfer shaft portions are inserted end-to-end and approximated, such that both abutting ends of the transfer shaft 12 portions are in physical contact with each other inside the collar. Therefore, there is no relative axial movement of the two adjacent ends of the transfer shaft 12 portions within the collar. Thus, the longitudinal force transmission between the proximal end of the tube or rod 16

receiving the endwise compressive force C to the proximal end of the stent 6 is optimised.

The proximal end of the distal portion of the stent delivery system, as shown in Fig. 2, comprises an adaptor 20 having two lumens 22,24 for effecting the rapid-exchange configuration. The guidewire 2 exits the distal portion of the stent delivery system through a guidewire port 24 of the adaptor 20, so as to be exposed outside the stent confining sheath 4 to enable the rapid exchange. The guidewire port 24 is preferably off-centre of the adapter 20. The orifice of the second lumen 22 is defined by a pipe 18.

Referring to Fig. 2, the rod 16 being part of the pusher assembly and preferably made of metal abuts at a distal end thereof the proximal end of the transfer shaft 12 inside the connection piece 14. Its proximal end extends beyond the proximal end of the pipe 18. The rod 16 extends distally from the distal portion of the delivery system through the second lumen 22 of the adapter. At its proximal end it receives the endwise compressive force C.

In a further embodiment of the disclosed system, not shown, the rod 16 can be provided as a tube with a lumen running from the proximal end of the system to the lumen of the pipe 18.

In both embodiments, the pipe 18 is connected to the adaptor 20 and furthermore, the adaptor 20 is connected to the outer sheath 4. The integrity of this connection is somewhat crucial for the proper functioning of the delivery system, since the outer sheath 4 is usually made of a polymeric material whereas the adaptor 20, the rod 16 (or tube), and the transfer shaft 12 are preferably made of metal, such as stainless steel. Metal-to-polymer connections are normally made by means of an adhesive.

To permit sufficient rigidity and to provide a rupture-resistant connection of the pipe 18 through the adaptor 20 to the outer sheath 4, the pipe 18 is advantageously welded into a

recess of the adaptor 20. Tension studs 20A, as shown in Fig. 1A, are provided in the proximity of the distal end of the adapter 20 to engage along the entire circumference of the adapter 20 with individual strands of a braid 43 encapsulated by the polymeric material of the outer sheath 4. The tension studs 20A protrude radially outwardly into the interstices of the braid 43 to reduce the dependence on glue to prevent rupture of the connection between the adapter 20 and the outer sheath 4. The stud to braid link between the pipe 18 and the outer sheath 4 via the adapter 20 feature metal all the way from one end of the system to the other so that the risk that the adhesive joint between the adapter 20 and the outer sheath 4 may break is reduced and the strain suffered by the system in releasing a stent is also kept small (which should help in reducing the "breathing" phenomenon mentioned above). Other types of connections will be apparent to those skilled in the art and an explicit explanation thereof is therefore omitted.

When using the stent delivery system, a tensile force T acts on the pipe 18, thereby proximally displacing the outer sheath 4 to release the stent 6, and at the same time a compressive force C is received by the tube or the rod 16 at its proximal end and is transmitted to the transfer shaft 12 in order to prevent proximal displacement of the stent 6 during stent deployment.

Since the pusher element 8 provides a lumen for the guidewire, abuts the stent 6 in use and is supported axially by the transfer shaft 12, and since the stent 6 is self-expanding and so is pressing radially outwardly on the sheath 4, there is no need for an inner catheter to extend beyond the proximal end of the stent 6. The tapered tip 4A of the sheath 4 facilitates advance of the catheter system through a tortuous lumen of the patient's body. The tapered tip 4A also resists inadvertent or premature distal movement of the stent 6 relative to the sheath 4, such as when the delivery system is introduced into a narrow vessel inside the patient's body. In this way, the tapered tip 4A of the outer sheath 4 can act a distal stopper for the stent.

For a detailed description of such tapered tips and their use, see Applicant's WO 01/34061.

A distal marker carrier 10, itself carried on the pusher element 8, exhibits a length sufficient to project distally beyond the stent 6 and defines a lumen for the guidewire 2. In use, the guidewire 2 extends along an axial path which lies side by side with the transfer shaft 12, which shaft 12 is off the axis of the outer sheath 4. The proximal end of the distal marker carrier 10 is attached, conveniently by glue, to the inner surface of the pusher element 8 to fix its axial position. The proximal end of the distal marker carrier 10 has a flared end which facilitates distal advancement of the guidewire 2 through the pusher assembly of the delivery system. The fixing established by the glue and the flared end also reduces the likelihood of separation of the carrier tube 10 from the pusher element 8.

The distal marker carrier 10 carries a distal marker 26, such as a radiopaque marker, indicating the position of the distal end of the stent 6. The inner surface of the distal marker 26 is flush with the inner surface of the distal marker carrier 10 for undisturbed relative axial movement of the guidewire 2. Preferably, a particular heat treatment is employed to attach the distal marker 26 to the distal marker carrier 10, so that the position of the distal marker is confirmed, relative to the distal marker carrier 10. It is also conceivable to embed or swage the distal marker 26 into the distal marker carrier 10 because the material used for the distal marker carrier 10 is relatively soft, preferably a resin tube.

The distal marker carrier 10 is normally a polymeric tube whereas the pusher element 8, the transfer shaft 12, and rod 16A or tube 16B are normally made of metal, conveniently stainless steel. It is also conceivable to use other material combinations for these parts, such as nickel-titanium shape memory alloy for the transfer shaft 12 and a composition of platinum/iridium (90/10) for the pusher element 8.

The outer sheath 4 may also carry a marker band 27 such as one on its inner luminal surface just proximal of its tapered tip 4A, for marking the distal end of the outer sheath 4.

Some applications require a thicker guidewire 2, such as a 35 thou guidewire. In such cases, one may choose to omit the distal marker carrier 10. Otherwise, one may choose to locate the marker 26 distal of the distal end of the stent in the free volume 40 between the stent and the tip 4A, thereby minimising the consumption of lumen cross-section inside the stent lumen. The remaining structure of the pusher assembly can remain the same. Hence the versatility of the pusher assembly is increased because of its usefulness with guidewires of different diameters.

Figure 3 shows an isometric view of the adapter 20, preferably made of metal, such as stainless steel, which makes available the rapid exchange facility. The adapter comprises two lumens 22, 24 one of which is a guidewire lumen 22 and the other one of which permits the rod 16 or tube to exit the adapter. Lumen 24 of the adapter is defined by two opposing arcuate segments 23A and 23B. The pipe 18 is introduced into lumen 24 of the adapter 20 from the proximal end of the adapter which has the shape of a mushroom until it abuts the distal end of a recess (not shown). In this manner, the adapter does not need to have a circumferential side wall which encloses lumen 24 by 360°. Hence, the lateral dimensions are minimised. Furthermore, as shown in Fig. 3, tension pins (studs) 20A are provided on the outer circumferential surface of the distal portion of the adapter 20 engaging with the braid 43 which is encapsulated by the polymeric material of the outer sheath 4. Lumen 24 which is a guidewire lumen is located off-centre of the adapter 20 and allows the guidewire 2 to exit the delivery system to effect the rapid-exchange configuration. The adapter is preferably made of metal, such as stainless steel, but the use of other alloys is conceivable.

Referring now to Fig. 4, a cross-sectional view of the proximal portion of the stent delivery system is shown. The proximal portion is part of a pull-back device used for proximally retracting the outer sheath 4 to release the stent 6. The pipe 18 which is connected to the sheath 4 via the adapter 20 is linked to an adapter ring 36. A welded joint is preferably be used for the link but other types of joints may be used, such as glue or an interference fit etc. The adapter ring 36 is joint to a polymeric sleeve 38 fitted into the distal portion of a distal hub 40. As the distal hub is successively pulled back proximally with every squeeze on the trigger of the pull-back device (not shown), a proximal hub 46 at the proximal end of the rod 16 or tube is held stationary at the same time by a compressive force being transmitted from the proximal hub 46 via rod 16 and transfer shaft 12 to the pusher element 8. In this way, controlled release of the stent at a desired position inside the patient's body is achieved.

The proximal portion of the stent delivery system further provides the possibility to insert contrast fluid through the Luer-adapter 42 into the annulus between the distal hub 40 and a supporting member 44 being sealed by an O-ring 48 and connected to rod 16. The contrast fluid passes beyond the distal end of the distal hub 40, creeps through the gap between the adapter ring 36 and the rod 16 and emerges from the distal end of the pipe 18 finally to reach the distal end of the outer sheath 4 to get squirted out into the vessel of the patient's body.

The Luer-valve assembly 42 also comprises a safety lock for locking the axial movement of rod 16, (the subject of Applicant's PCT/EP02/06782 now published as WO-A-), which ensures safe transport of the packaged delivery system without the risk of inadvertent release of the stent and to enable the physician to interrupt the stent deployment process, when needed, without having to be concerned with the displacement of the stent whilst the physician is not holding the delivery system in his/her hands. The disclosure of PCT/EP02/06782 is hereby incorporated by reference.

The pusher assembly, as shown in Fig. 5, is destined to be used for an 18 thou guidewire 20. The entire pusher assembly is enclosed by an outer catheter 2 of an over-the-wire stent delivery system prior to deployment of the stent 6. In this condition the stent 6 is held in a radially compressed configuration by the same outer catheter 2. For deployment of the stent 6, the outer catheter 2 is withdrawn until the distal tip 63 is proximal of the proximal end of the stent 6.

The pusher assembly incorporates a catheter shaft 66, the distal end of which is connected to a transfer shaft 64. A pusher element 68 is connected to the distal end of the transfer shaft 64. During the course of stent deployment the distal end 69 of the pusher element 68 abuts the proximal end of the stent 6. Thus, the pusher element 68 serves as a stop for the stent 6 during stent deployment, to prevent proximal movement of the stent as the outer catheter 2 is withdrawn proximally.

The proximal end of the pusher element 68 is laser-welded to the distal end of the transfer shaft 64 and the same manner of connection is used for connecting the proximal end of the transfer shaft 64 to the distal end of the catheter shaft 66. For ease of connection, both the distal and the proximal ends of the transfer shaft are tapered and embedded in respective slots provided in the proximal end of the pusher element 68 and the distal end of the catheter shaft 66. The ends of the transfer shaft 64 are tapered such that the circular cross-section of the transfer shaft 64 between its ends is oblate at its ends, so that both ends can be fitted into respective slots of the adjacent pusher element 68 and catheter shaft 66, with the circumferential surfaces over a specific arc length of both oblated ends being flush with the circumferential surface of the pusher element 68 and the catheter shaft. The slot provided in the proximal end of the pusher element 68 has an axial length which extends from the proximal end of the pusher element beyond mid-way along the axial length of the pusher element 68. The length of the slot in the distal end of the

catheter shaft 66 is much the same length, and long enough to ensure that a sufficient connection between the transfer shaft 64 and the catheter shaft 66 is obtained. Such shaping of the two ends of the transfer shaft and the pusher element 68 and the catheter shaft 66 maximises the flow of injected contrast fluid, since the fluid does not meet any unnecessary barrier when travelling along the length of the transfer shaft. In other words, the resistance to the flow of the injected contrast fluid is minimised.

A connection piece such as a tube 78 at an intermediate position of the transfer shaft 64 enables the accommodation of different stent lengths in an unchanged sheath 2 and catheter shaft 66, by an appropriate adjustment in the length of the transfer shaft portions in accordance with the length of the respective stent. The two cut-to-length transfer shaft portion ends bridged by the connection tube 78 are either glued or soldered to the connection tube 78. The connection tube 78 can be no more than a collar into which the two adjacent ends of the separate transfer shaft portions are inserted and approximated, such that both ends of the transfer shaft are in physical contact with each other inside the collar. Therefore, there is no relative axial movement of the two adjacent ends of the transfer shaft portions within the collar.

A distal marker carrier 74, itself carried on the pusher element 68, exhibits a length sufficient to project distally beyond the stent 6 and defines a lumen for the guidewire 20. In use, the guidewire 20 extends along an axial path which lies side-by-side with the transfer shaft 64 which is off the axis of the outer sheath 2. The proximal end of the distal marker carrier 74 is attached, conveniently by glue, to the inner surface of the pusher element 68 to fix its axial position. The proximal end of the distal marker carrier 74 has a flared end for guided distal advancement of the guidewire 20 through the pusher assembly of the delivery system. The fixing established by the glue and the flared end also reduces the likelihood of separation of the carrier tube 74 from the pusher element 68. The distal marker carrier 74 carries a distal

marker, such as a radiopaque marker 72, indicating the position of the distal end of the stent.

The distal marker carrier 74 is a polymeric tube whereas the pusher element 68, the transfer shaft 64, the catheter shaft 66 and the connection tube 78 are made of metal, conveniently stainless steel. It is also conceivable to use other material combinations for these parts, such as nickel-titanium shape memory alloy for the transfer shaft and a composition of platinum/iridium (90/10) for the pusher element 68.

The distal marker 72 can be embedded or swaged into the distal marker carrier 74 because the material used for the distal marker carrier 74 is relatively soft, preferably a resin tube.

Some applications require a thicker guidewire 20, such as a 35 thou guidewire. In such cases, the distal marker carrier 74 may need to be omitted, as shown in Figure 6. The remaining structure of the pusher assembly can remain the same. Hence, the versatility of the pusher assembly is increased because of its usefulness with guidewires of different diameters.

Reverting to the embodiment shown in Figure 5, however, a thicker guidewire can be accommodated if the distal marker 72 is moved to a position just distal of the distal end of the compressed stent 6. To resist bowing of the pushing wire 64, it can be bonded to an additional short length of tube mounted distally to the catheter shaft 66. The bonding could be with glue. The mounting could be a telescopic mounting within the distal open end of the shaft 66, the tube length glued to the said distal end and extending, cantilevered, distal of the distal end with the pushing wire glued to its outside cylindrical surface. Denial of bowing of the pushing wire within the lumen of the outer catheter should eliminate any substantial "lost motion" when the outer catheter is initially pulled back proximally, and the pushing wire 64 goes into compression, in the initial stages of stent release.

Drawing figures 7, 8 and 9 show a third embodiment of the disclosure which is, in some respects, a hybrid of the embodiments of Figures 5 and 6.

In Fig. 7 there is an inner catheter 140 of polymeric material, glued inside the stainless steel shaft 116 and extending distally to a distal tip zone 142 which lies distal of the stent 6. Swaged around this distal tip zone is a distal marker 112, lying just distal of a distal end of the stent 6. For the remaining distal tip portion 142 of the inner catheter 140, lying distal of the distal marker 112, the diameter is slightly increased, as can best be seen in Figure 8, which increases the security with which the marker 112 is retained on the inner catheter shaft 140, with corresponding reduced likelihood of loss of the marker 112 by slipping off the distal end of the catheter 140. As can be seen, the guidewire 20 extends through the shaft 116 and inner catheter 140, being a relatively snug fit within this lumen.

Lying on the outside cylindrical surface of the inner catheter 140 is a transfer shaft 114 and connector 118. With a sequence of glue spots 144, the transfer shaft 114 is bonded to the inner catheter shaft 140, thereby preventing any tendency for the transfer shaft 114 to bow when it is put in longitudinal compressive tension for release of the stent 6.

As shown in Figure 8, at the distal end of the transfer shaft 14 is the pusher 108 and this carries, on its outside cylindrical surface, an additional thin platinum/iridium radiopaque marker band 146. A further marker 148 is integrated in the thickness of the outer catheter wall 2, just distal of the stent 6, overlying the marker 112 on the inner catheter 140. During progressive deployment of the stent, by proximal withdrawal of the outer catheter 2, the radiologist will be able to observe the progressive movement of the outer catheter marker 48, proximally away from the distal stent marker 112 and towards through and beyond the proximal marker 146.

In the following, some of the advantages of the pusher assembly of PCT/EP02/07435 are elucidated.

Since the catheter shaft tube 116, the pusher element 108 and the guidewire 20 are all of metal, friction between the guidewire and the stent delivery system is low, and so PTFE or other special low-friction coatings can be omitted, thereby saving manufacturing costs.

During release of the stent, the transfer shaft remains under a more or less constant compressive strain once it has undergone a certain amount of bowing within the lumen of the outer catheter sheath 2 as a result of the proximal withdrawal of the outer sheath. This bowing typically reduces the distance between the pusher element 108 and the catheter shaft 114 by approximately 5mm. The compressive strain suffered by the transfer shaft 14 remains constant throughout the deployment of the stent for as long as the outer catheter 2 is in axial tension. Hence, a precise placement of the stent with respect to the stenting site can be achieved and no significant "breathing", as mentioned above, to be observed.

In the following, some of the advantages of the PCT/EP02/07435 stent delivery system, whether or not it has a rapid exchange configuration, are elucidated.

The delivery system takes full account of the previously known advantages of a rapid-exchange delivery system, such as easy removal and exchange of the delivery system, while the guidewire remains at a desired position within the patient's body.

The simplified internal structure of the distal portion of the delivery system enables improved visualisation of the stenosis due an increased volume flow of contrast fluid with each pulse.

Furthermore, during release of the stent, virtually no proximal movement of the stent is seen, while the outer sheath is being withdrawn proximally. The system can provide a metal structure

all the way from the proximal end of the pull back unit receiving the endwise compressive force to the pusher element to keep the stent in place during stent deployment. Therefore, no bowing of the force-transmitting components is caused during stent release. Furthermore, the component that is withdrawn proximally, including the outer sheath 4, can also exhibit metal-to-metal connections end-to-end.

As shown in the illustrated embodiments, the length of the transfer shaft, which preferably amounts to a maximum of 3cm, is relatively short compared to its diameter, so that appreciable bowing is suppressed. In addition, the transfer shaft confined by the outer sheath and lying side-by-side to the guidewire inside the lumen of the outer sheath has nowhere to go when it seeks to bend under compression during stent release, thereby preventing shortening of the distance between the pusher element and the distal end of the rod. Hence, more precise placement of the stent with respect to the stenting site can be achieved. Furthermore, assembly of the system is facilitated and manufacturing cost are reduced.

The system is further adaptable to guidewires of different diameters, which enhances the versatility of the system and its acceptability to the practitioner.

It is worthwhile to mention that the delivery system may be used in connection with a guiding catheter. The physician attempting to bring a stent to a stenosis site inside the patient's body uses an outer guide catheter to be first introduced in the patient's body. Once the guide catheter has been properly placed, a guidewire is introduced through the guide catheter lumen along which the delivery system is advanced to the site of the stenosis in a next step. Here, the contrast fluid to be used to visualise the stenosis can be injected, if the physician prefers to do so, through the gap between the internal surface of the guide catheter and the external surface of the delivery system. Hence, the annulus between the pipe 18 and the rod 16 or tube, shown in Fig. 2, can be further reduced in order to minimise the transverse

dimension of the delivery system, which is advantageous in terms of both the recovery of the patient and the handling comfort for the physician.

Prior to use of the delivery system, as is the case for any devices used to inject fluids into the human body, the delivery system needs to be vented and primed, i.e. the system is flushed with a biocompatible solution, such as a sodium chloride solution, until all the air confined inside the system has been driven out of the system. The disclosed delivery system may be flushed with such a solution from the distal tip of the delivery system prior to use. This may enhance the practical usefulness of the delivery system, since the guidewire is also inserted into the delivery system from the distal end of the system, so that the physician can carry out the flushing and the guidewire insertion in what may amount to a single operation. This allows the physician to choose the alternative with which he/she has grown most comfortable and which is best suited for the specific circumstances.

Summary of the Present Invention

The present invention is an improvement in, or modification of, the system disclosed in Applicant's earlier PCT/EP02/07435. The system of the present invention can be used for purposes other than delivering a self-expanding stent. For example, it can deliver to a site of surgery an angioplasty balloon, a filter for a bodily fluid, a diagnosis element, an ablation element, a laser treatment element or an electrode element. Other devices will occur to those skilled in the art. Further:
i. the distal end of the outer sheath need not be tapered. Any taper could be provided on an inner shaft instead;
ii. the proposals of PCT/EP02/07435 for modular construction need not be included.

The present invention is defined, in one aspect, in claim 1 below. In another aspect, the present invention features the step of imposing a radially-inward taper on the proximal end of a sleeve at the distal end of a trans-luminal, guidewire-

advanced, rapid-exchange surgical delivery device, the taper defining a proximal guidewire lumen exit port.

In one embodiment, a mandrel is used to define the exit port, as the taper is imposed. The taper can be imposed by a combination of heat and radially-inward pressure. Heat-shrinking the sleeve in a proximal end zone thereof is one possibility to impose the said taper. Heat shrinking with the mandrel in place is particularly preferred. Heat-shrinking the sleeve over a distally-directed shoulder of the delivery system is an effective way to build a push-compatible connection between the distal end of a shaft of the delivery device and the proximal part of the sleeve of the device.

If the sleeve is reinforced with filamentary material such as a metal braid, and if the sleeve defines an atraumatic tip of the surgical delivery device, then it will normally be appropriate to terminate the filamentary material proximal of the inwardly-tapering tip. At the inwardly tapered proximal end zone of the sleeve, it may be attractive for a metallic braid or other filamentary reinforcing material to remain, so as to enhance the connection in tension between the sleeve and the shaft. In the case of a mesh embedded in the wall thickness of a sleeve of synthetic polymeric, heat-softenable material, heat-forming of the proximal taper can allow the crossing angle of the braided filaments to change, as the tube defined by the braid in the tapered proximal zone reduces its diameter and increases its length. As mentioned above, such filamentary reinforcement, especially braiding, can help to obviate or ameliorate the "breathing" phenomenon users experience when trying to deploy, in a series of sleeve-withdrawing pulls, a self-expanding stent into a bodily lumen.

In preferred embodiments of the delivery device of the present invention, its primary shaft is a tube. That tube may contain an inner shaft which, in use, slides relative to the tube, whereby the imposition of endwise compression on the inner shaft, and endwise tension on the tube, withdraws the sleeve proximally relative to the distal end of the inner shaft.

Typically, the distal end of the inner shaft is configured as a pusher, for maintaining the position of a surgical element at the site of surgery, during proximal withdrawal of the sleeve to expose the surgical element to the bodily lumen along which the delivery device has been advanced to the site of surgery. The surgical element in this case could be a self-expanding stent, typically of nickel-titanium shape memory alloy.

Conveniently, the guider tube of the device extends distally beyond the distal end of the primary shaft of the delivery device. It may be useful to include a guidewire guider hose which has a proximal end and a distal end, and a lumen which is contiguous with the lumen for the guidewire in the guider tube, the proximal end of the guider hose being contiguous with the distal end of the guider tube. Conveniently, the distal end of the guider hose is flared radially outwardly, towards the luminal wall of the sleeve so that, when the proximal end of a guidewire is back-loaded into the distal end of the sleeve of the delivery device, the outward taper gathers the proximal end of the guidewire into the lumen of the guider hose (and thereafter through the guider tube and out through the proximal guidewire lumen exit port).

It is contemplated that the structure of the distal end of the inner shaft, through to the distal tip of the delivery device, may be freely adopted from the inner shaft constructions disclosed in Applicant's earlier PCT/EP02/07435, including such features as an annular surgical element pusher which defines a portion of the length of the guidewire lumen and which is aligned with the lumen for the guidewire at the distal end of any guider hose. The pusher might carry a carrier tube which extends distally from the annular pusher and itself defines a portion of the length of the guidewire lumen. The carrier tube might carry a radiopaque marker band at or near its distal end and the carrier tube might extend proximally from the annular pusher into a portion that tapers outwardly towards the luminal wall of the sleeve for guiding into the carrier tube the distal end of a guidewire advanced distally from the proximal guidewire exit port. There might be a connector between the

inner shaft and the annular pusher, for facilitating modular assembly of delivery devices to suit different lengths of surgical element. Specifically, it will often be advantageous to find an unbroken metal strand running from the proximal end of the inner shaft to the annular shaft that is to engage on the surgical element due to be deployed from the delivery device.

For a better understanding of the present invention, and to show more clearly how the same may be carried into effect, reference is made, not only to drawing figures 1 to 9 described above, but also to further drawing figures included in the specification as follows:

Fig. 10 shows a longitudinal diametral section through the distal end of a surgical delivery device in accordance with the present invention;
Fig. 11a is such a section, at greater magnification, of the distal portion; and
Fig. 11b the proximal portion, of the distal end shown in Fig. 10.

Component parts shown in Figs. 10 and 11, to the extent that they correspond to component parts in the earlier drawing figures, are identified by the same reference sign.

Looking at Fig. 10, what is shown is the distal part of a stent delivery system having a total length of the order of 1300 mm, the portion shown in Fig. 10 amounting to the distal-most 300 mm of the length of the entire system. As we see, this distal portion has an overall diameter of 5F (French) whereas the shaft portion of the length of the system, proximal of the distal sleeve 4, has an overall diameter of about 1.8F.

Now referring to Fig. 11, for the details of construction of the system, its primary shaft 18 takes the form of a stainless steel hypo-tube. To the distal end of this tube is welded a stainless steel guidewire guider tube 200 which has a proximal end 202, a lumen, and a distal end 204 which is located

distally of the distal end 206 of primary shaft 18. Form-fitted over the distal end of the guider tube 200 is the proximal end 208 of a synthetic polymeric guidewire guider hose 210 which defines a guidewire lumen and has a distal end 212 which is radially outwardly flared towards the luminal surface 214 of the sleeve 4 of the device.

Within the primary shaft 18 is an inner shaft 16 which extends distally forward, past the outward tapered end 212 of the guider hose 210, as far as an annular pusher element 8, to which it is welded. The inner shaft 16 is conveniently of stainless steel and conveniently welded to the annular pusher 8 which may also be of stainless steel. The pusher 8 can comprise, or even consist, radiopaque material such as tantalum, in order that the pusher ring 8 may serve as a radiopaque marker band. The annular pusher 8 carries a carrier tube 74, which itself carries a radiopaque marker band 72 and has a proximal end 220 tapered radially outwardly towards the luminal wall surface 214 of the sleeve 4, as described above in relation to the earlier drawing figures.

Turning now to features that distinguish the present invention from the disclosure of PCT/EP02/07435, it is to be noted that the sleeve 4, at its proximal end 222, is tapered inwardly, to become form-fitted around the external cylindrical surface 224 of the primary shaft element 18. Figures 10 and 11 show guidewire 2 in chain-dotted outline and it is to be noted that this location of the guidewire 2 extends through a proximal guidewire lumen exit port 226 found within the tapered proximal portion 222 of the sleeve 4. One convenient way to form the exit port 226 is with a mandrel (not shown) that takes the path of the guidewire, in the lumen of the guider tube 200, but which penetrates also the sleeve 4, and the embedded braiding 228, after the cylindrical wall of the sleeve 4 has been deformed over the proximal end 202 of the guider tube 200. With the mandrel having penetrated the sleeve wall and braiding, and extending into the guider tube 200 from its proximal end 202, the sleeve 4, at its proximal end, can be heat-shrunk down onto the primary shaft tube 18. After such

heat shrinking, the mandrel can be removed, leaving the guidewire exit port 226 fully formed in the heat-shrunk proximal sleeve end, and aligned with the lumen in the guider tube 200.

Looking along the length of the sleeve 4, distally of the inwardly-tapered proximal zone 222, and at the zone 230 immediately distal of the distal end 206 of the primary shaft tube 18, we find another zone of radially inward heat shrinkage, around that part of the length of the guider tube 200 which protrudes distally beyond the distal end 206 of the primary shaft tube 18, yet proximal of the distal end 204 of the guider tube 200. This inwardly shrunk zone 230 is effective to resist any tendency of the sleeve 4 to slide proximally over the guidewire guider tube 200, for example when the delivery system is subject to compressive stress in the primary shaft tube 18, as when it is being pushed from its proximal end to urge the distal end, with the sleeve 4 along a bodily lumen.

The inward shrinkage can be manifested in a reduced outer diameter corresponding to greater frictional engagement between the sleeve and the shaft. Alternatively, or additionally, the sleeve inner diameter can be reduced, which would yield on its luminal surface a shoulder to resist proximal slippage of the sleeve in the shaft.

Fig. 11 shows a self-expanding stent 6 within the sleeve 4, and a tapered distal end 240 of the sleeve 4 as with the embodiments described above in relation to figures 1 to 9. Note that the embedded metallic filament braiding 228 in the sleeve 4 stops proximally short of a tapered atraumatic tip 240. Note that the atraumatic tip 240 of the sleeve 4 tapers down to a leading annulus 242 of the entire system, which has a diameter adapted to fit with relatively small clearance, or even snugly, around the cylindrical wall surface of the guidewire 2.

To assemble the stent 6 and the delivery device, the sleeve 4 is prepared with its proximal end not yet heat-formed. The stent 6 is introduced into the sleeve 4 at the open proximal end, and advanced along the length of the sleeve until it reaches its delivery disposition just proximal of the distal tip of the sleeve 4. Then the assembly of pusher 8 in a shaft 12/16 and primary shaft tube 18 is assembled together and all introduced as a sub-assembly into the open proximal end of the sleeve 4. Then a mandrel is advanced through the wall of the sleeve 4, as that wall lies over the proximal end of the guide tube end 202 of the guider tube 200, and advanced into the lumen of the guider tube 200. then, with the mandrel in place, the proximal end 222 of the sleeve 4 is heat-shrunk down onto the outside cylindrical wall 224 of the primary shaft tube 18, also with heat and radial inward pressure at the annulus 230 of the sleeve 4 just distal of the distal end 206 of the primary tube 18.

Those skilled in the art will be familiar with the usual arrangements at the proximal end of the coaxial tube 18/shaft 16 arrangement, for deploying the stent 6 by proximal retraction of the sleeve 4. Further details are available from present drawing Fig. 4 and the corresponding text above. After proximal withdrawal of the sleeve 4, to deploy the self-expanding stent 6, the entire delivery system may be withdrawn from the bodily lumen and the body of the patient. It will be appreciated that the only component withdrawn proximally along the lumen of the expanded stent 6 is the carrier tube 74, which has minimal structural features to interfere with any bodily tissue protruding radially inwardly into the lumen of the expanded stent 6, through its expanded interstices. It will be appreciated that proximal withdrawal of the sleeve 4 causes the taper tip 240 to open up to a more cylindrical configuration, with a distal opening 242 big enough to pass over the abluminal surface of the stent 6 being deployed. It may be convenient to provide the taper tip 240 of the sleeve 4 with parting zones which are elongate in the axial direction of the system, enabling the taper tip 240 to split into two or more part-circumferential portions in relief of hoop stresses imposed

within the taper tip 240 by its being pulled proximally over the stent 6. Any such parting will relieve the hoop stress and tensile stress within the sleeve 4 in general, thereby reducing the amount of tensile force necessary to be applied to the primary tube 18 at its proximal end, and in turn reducing the level of compressional stress carried by the inner shaft 16 and its continuation 12, as well as by the stent pusher 8.

It will be evident to skilled readers that the details of construction of the inner shaft 16 distal of the primary tube 18 can be selected to fit with whatever surgical element is to be delivered by proximal retraction of the sleeve 4. For example, in place of the stent might be means to direct a laser beam to a zone of bodily tissue within a site of surgery or one or more electrodes for electrical treatment of such tissue. Otherwise, there could be on the distal end of the inner shaft 16 a filter for bodily liquid flowing within the lumen along which the delivery system is advanced. For example, one might wish to use the illustrated system to deploy a filter for blood in the carotid artery. Such filters are known, and conveniently are made of nickel-titanium shape memory alloy. Otherwise, one envisages the provision of inner shaft 16 in the form of an inflation lumen, and the provision of a treatment balloon, such as an angioplasty balloon, on the distal end of the shaft tube 16. Other uses of the delivery system illustrated in Figs. 10 and 11 will be evident to those skilled in the art.

The system illustrated in Figs. 10 and 11 shows three radiopaque markers 8, 72 and 27, whereby progressive proximal withdrawal of the sleeve 4 reveals progressive proximal movement of radiopaque band 27 from a position overlying band 72 to a position level with, or proximal of band 8. Again, it will be evident to skilled readers, that other arrangements of radiopaque marker bands are possible and would be selected to suit the individual circumstances in which the delivery system is to be employed.

Further, skilled readers will appreciate that technical features drawn from one or other of the embodiments shown in Figs. 2 to 9 can be carried into the embodiment of Figs. 10 and 11. For example, push rod 12 can be made modular, to suit different lengths of stent 6, as explained above, and carrier tube 74 could be omitted entirely, especially if the system does not require the presence of the radiopaque marker band 72 at the distal end of the surgical device 6. Other variations and modification will be apparent to those skilled in the art, who will appreciate that the drawings show only individual ones of a multitude of different embodiments within the scope of the claims that follow.

Claims.

1. A trans-luminal, guidewire-advanced, rapid-exchange surgical delivery device having a proximal end, a primary shaft and a distal zone to be advanced over the guidewire along a bodily lumen to a site of surgery; and

characterised by:

i. a guidewire guider tube that defines a guidewire lumen, said tube lying within the distal zone attached to one side of the primary shaft and having a proximal end opening which lies to one side of the shaft;

ii. a sleeve which defines a lumen to receive a surgical element distal of the guider tube, the sleeve having a proximal end which is form-fitted over the primary shaft and has a radially inwardly tapering portion proximal of the proximal end of the guider tube, said inwardly tapering portion defining a proximal guidewire lumen exit port.

2. Device as claimed in claim 1, characterised in that said primary shaft is a tube.

3. Device as claimed in claim 2, characterised in that said tube contains an inner shaft which, in use, may slide relative to the tube, whereby the imposition of endwise compression on the inner shaft and endwise tension on the tube may withdraw the sleeve proximally relative to the distal end of the inner shaft.

4. Device as claimed in claim 3 wherein the distal end of the inner shaft is configured as a pusher, to maintain the position of said surgical element at said site of surgery during proximal withdrawal of the sleeve to expose the surgical element to the bodily lumen.

5. Device as claimed in claim 4 including the surgical element.

6. Device as claimed in claim 5 wherein the surgical element is a self-expanding stent.

7. Device as claimed in any one of the preceding claims wherein the sleeve is reinforced by filamentary material within its wall thickness.

8. Device as claimed in claim 7 wherein the filamentary material is braided material.

9. Device as claimed in claim 7 or 8 wherein the filamentary material stops distally short of the distal end of the sleeve.

10. Device as claimed in any one of the preceding claims wherein the distal end of the sleeve is tapered inwardly to provide the device, at least prior to its arrival at the site of surgery, with a more or less atraumatic tip.

11. Device as claimed in any one of the preceding claims wherein the proximal end of the sleeve is form-fitted by the application of heat and radially inward pressure.

12. Device as claimed in any one of the preceding claims wherein the sleeve includes a push zone through which an endwise compression force imposed on the proximal end of the primary shaft can be transferred to the sleeve for advancing the sleeve along the bodily lumen to the site of surgery.

13. Device as claimed in claim 12 wherein the push zone corresponds to an annulus in which the sleeve has a reduced outside diameter relative to its diameter immediately proximal of said push zone.

14. Device as claimed in claim 12 or 13 wherein the push zone corresponds to an annulus in which the sleeve has a

reduced inside diameter relative to its inside diameter immediately proximal of said push zone.

15. Device as claimed in claim 12, 13 or 14 wherein the push one is found immediately distal of the distal end of the primary shaft.

16. Device as claimed in any one of the preceding claims wherein the guider tube extends distally beyond the distal end of the primary shaft.

17. Device as claimed in any one of the preceding claims and including a guidewire guider hose having a proximal end and a distal end, said proximal end being contiguous with the distal end of the guider tube.

18. Device as claimed in claim 17 wherein the distal end of the guider hose is flared radially outwardly, towards the luminal wall of the sleeve.

19. Device as claimed in claim 18 as dependent on claim 3, or any of claims 4 to 16 as dependent on claim 3, wherein the inner shaft extends distally beyond the distal end of the guider hose, along a path between the abluminal wall of the guider hose and the luminal wall of the sleeve.

20. Device as claimed in claim 19 wherein the distal end of the inner shaft carries an annular surgical element pusher which defines a portion of the length of the guidewire lumen which is aligned with the lumen for the guidewire at the distal end of the guider hose.

21. Device as claimed in claim 20 wherein the annular pusher carries a carrier tube which extends distally from the annular pusher and itself defines a portion of the length of the guidewire lumen.

22. Device as claimed in claim 21 wherein the carrier tube carries a radiopaque marker band at or near its distal end.

23. Device as claimed in claim 21 or 22 wherein the carrier tube extends proximally from the annular pusher sufficiently far to define a portion which tapers outwardly towards the luminal wall of the sleeve, for guiding into the carrier tube the distal end of a guidewire advanced through the guidewire lumen distally, from the proximal exit port.

24. Device as claimed in any one of claims 19 to 23, wherein the inner shaft includes a connector, located axially between the distal end of the primary shaft and the annular pusher, said connector permitting adjustment of the axial position of the annular pusher relative to the distal end of the sleeve, during assembly of the device, to cater for different lengths of the surgical element.

25. Device as claimed in claim 24 wherein the inner shaft comprises a distal portion of solid cross-section and a proximal tubular portion, the tubular portion extending within the primary tube shaft and distally therefrom, to said connector, or to a point proximal of said connector.

26. Device as claimed in claim 25 wherein the inner shaft exhibits an unbroken metal strand as far as the annular pusher

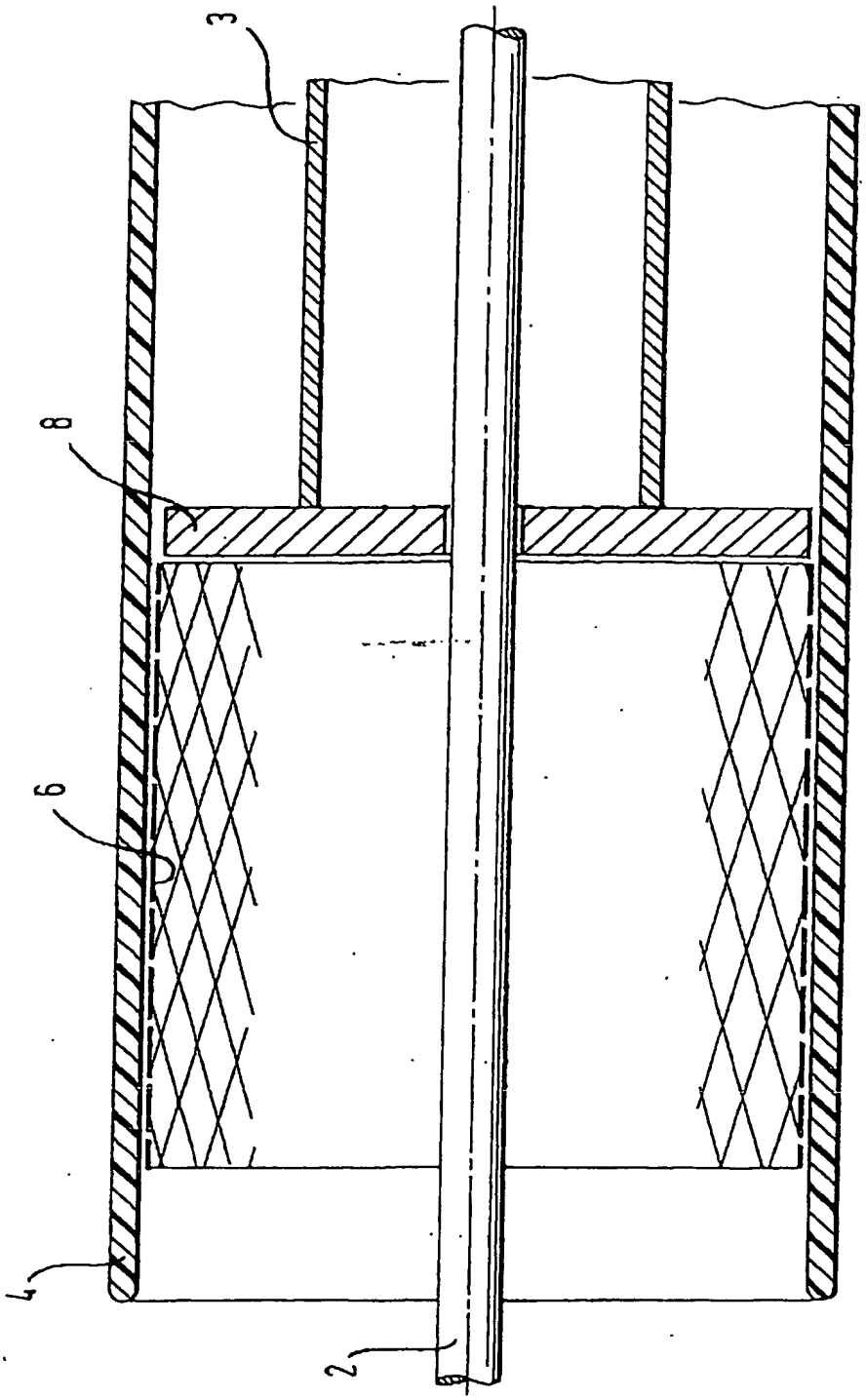
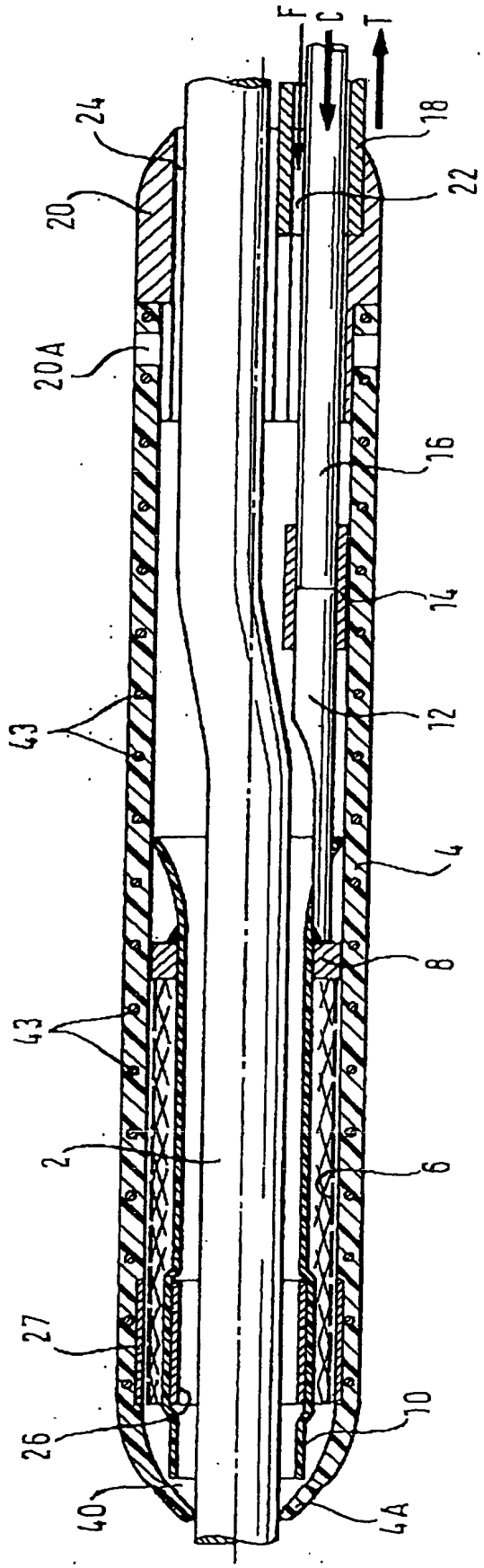


Fig. 1

Fig. 2



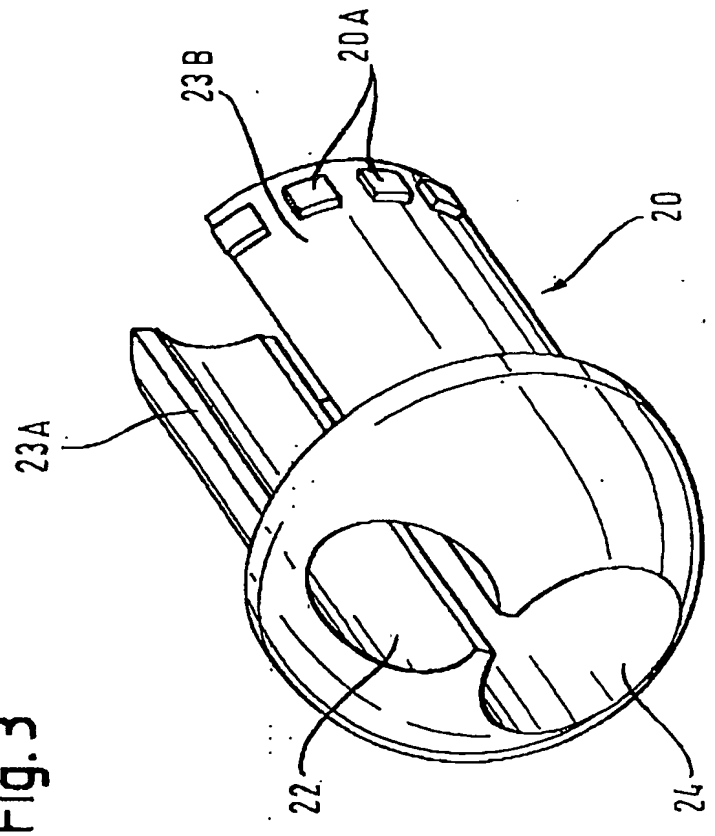


Fig.3

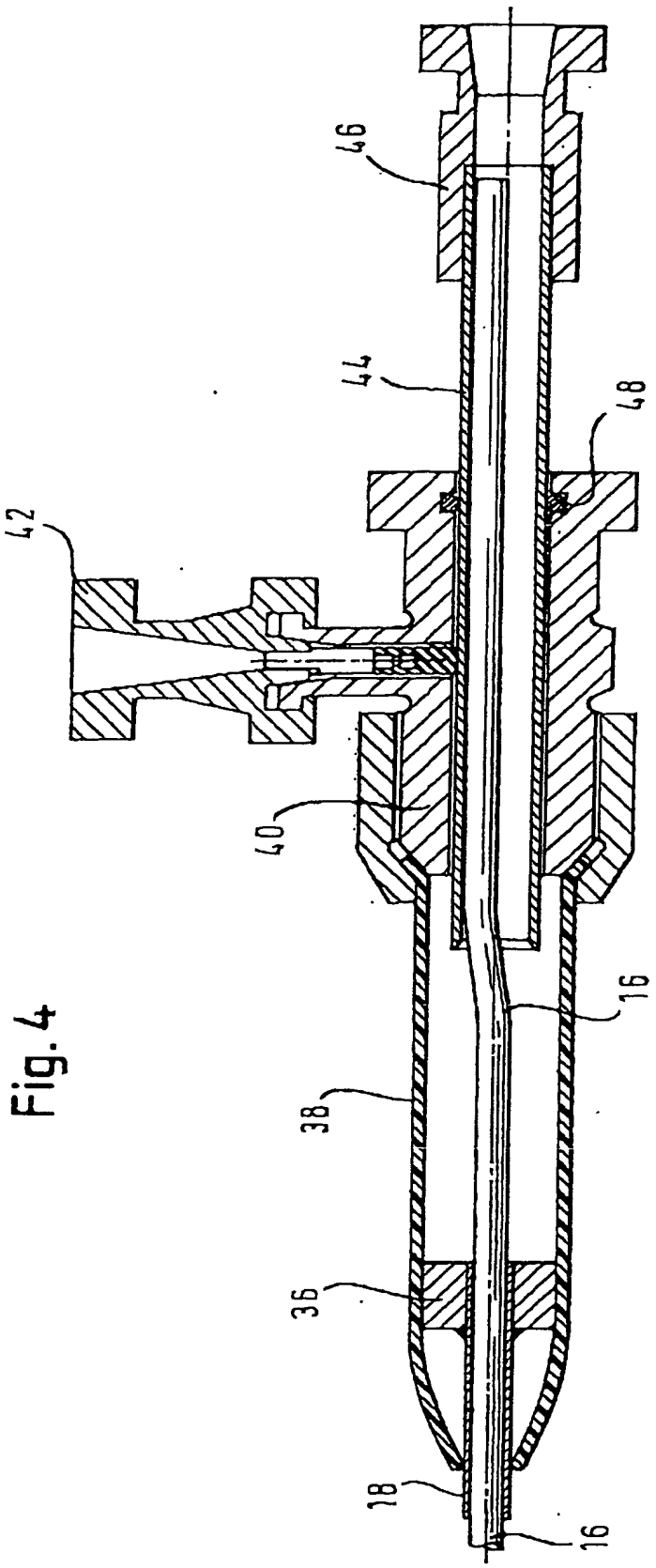
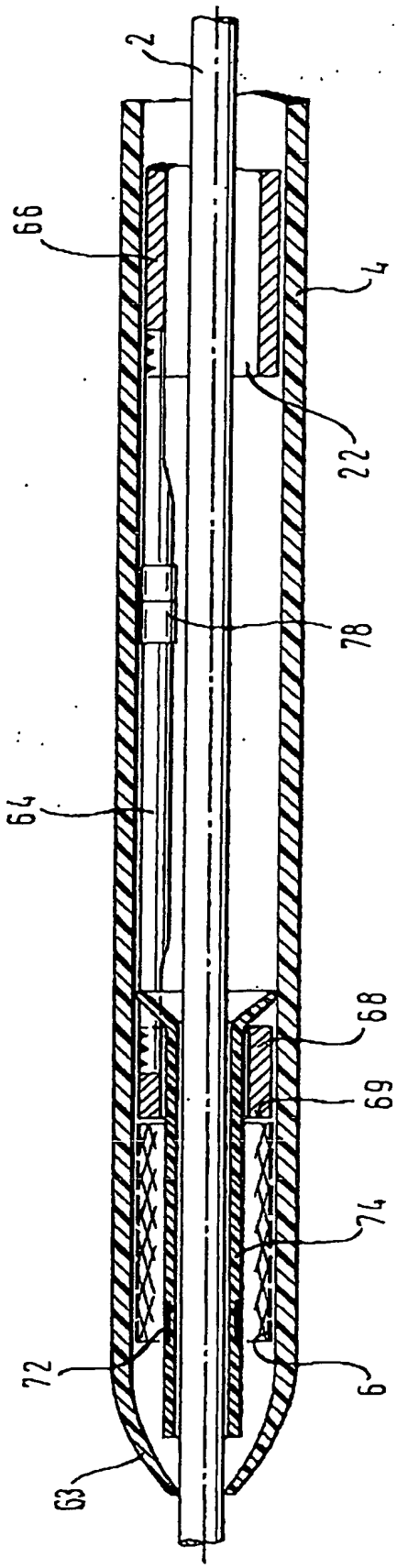


Fig. 4

Fig.5



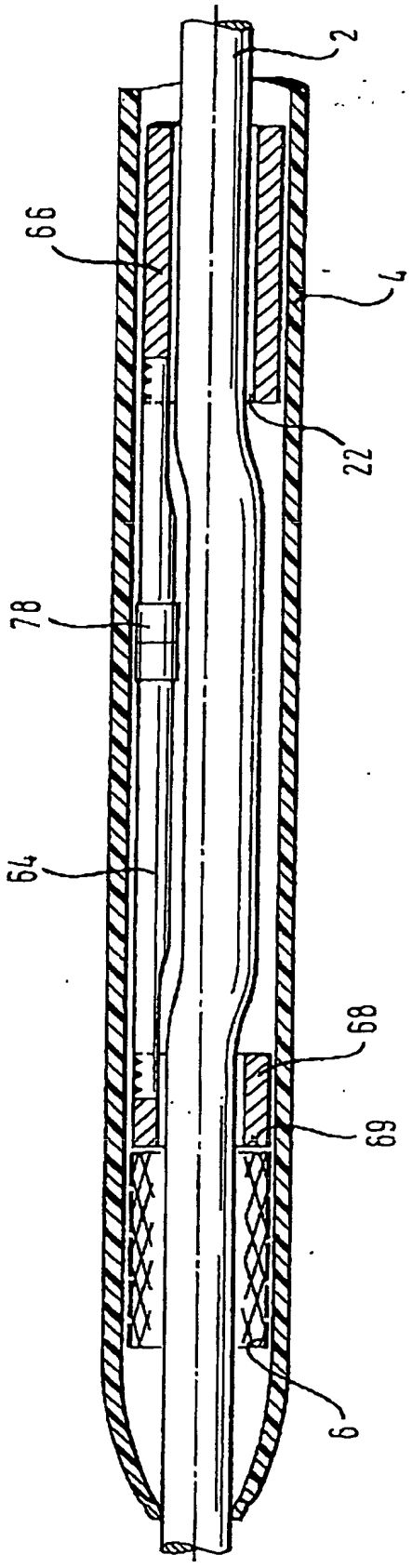


Fig.6

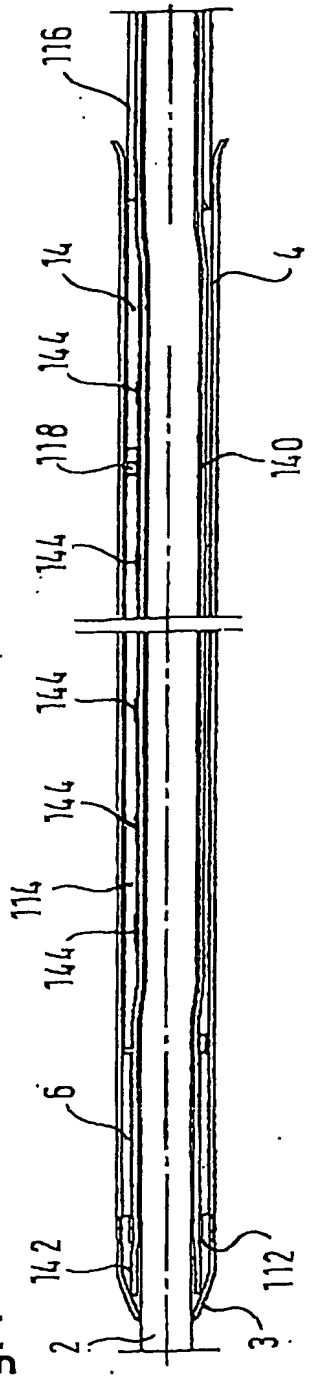


Fig. 7

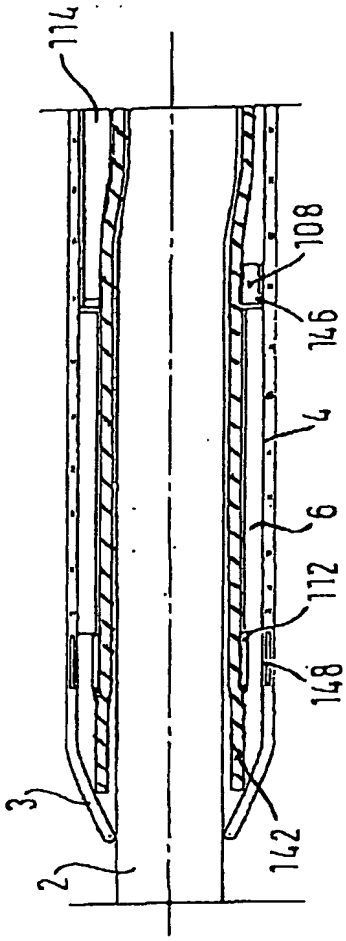


Fig. 8

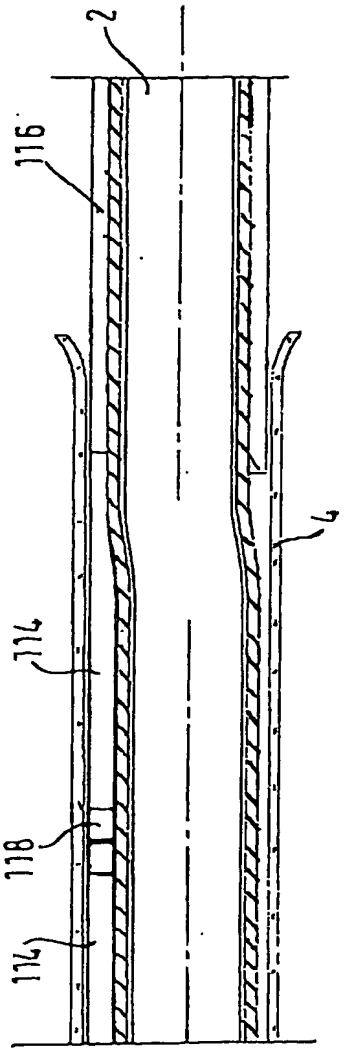


Fig. 9

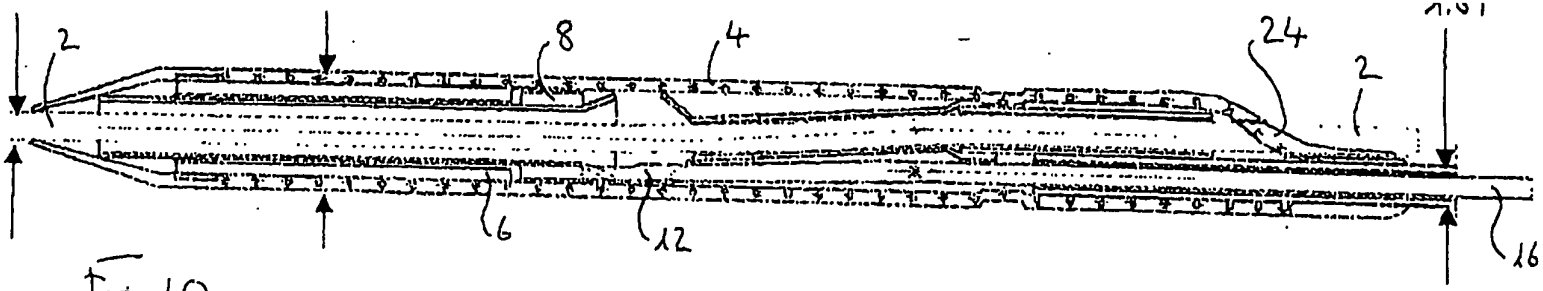


Fig 10

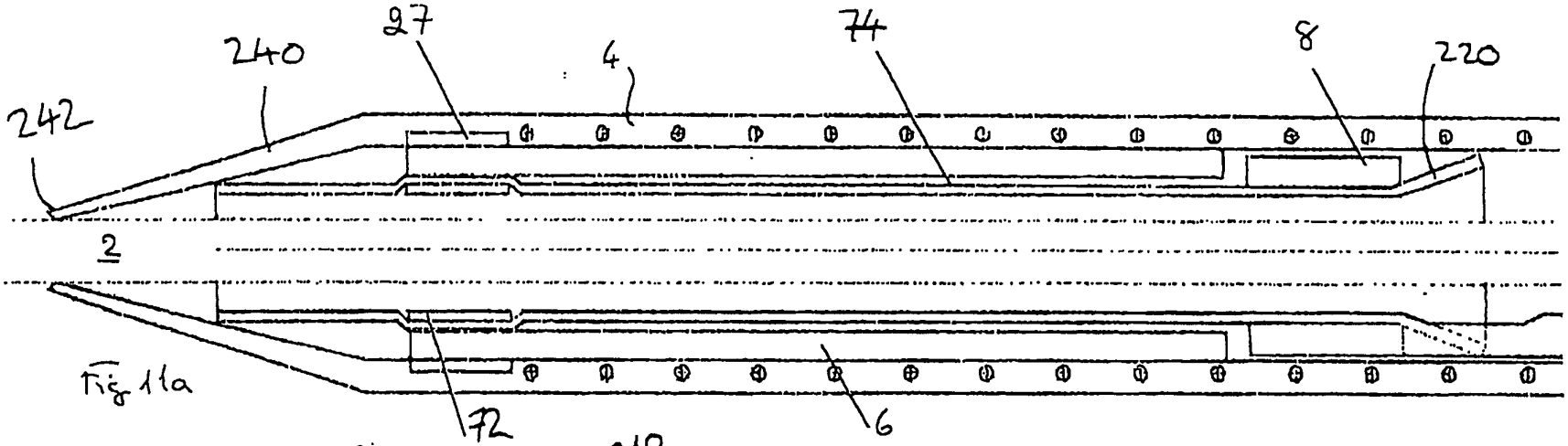


Fig 11a

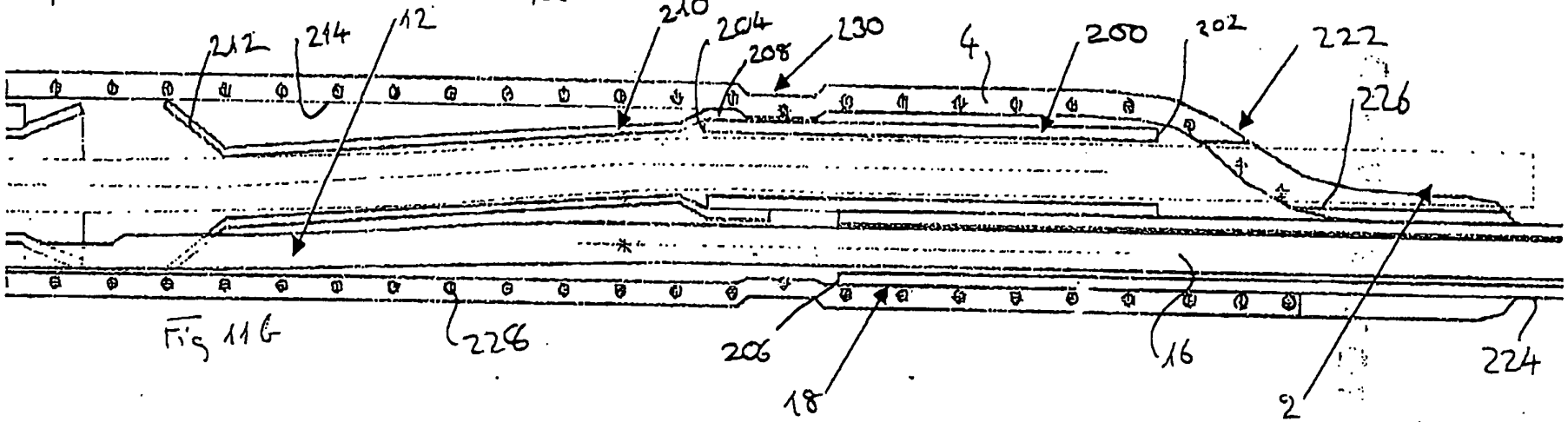


Fig 11b